



AUDIT REPORT FOR ROMANIA FEBRUARY 21 THROUGH MARCH 3, 2000

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Romania's meat inspection system from February 21 through March 3, 2000. The three establishments certified to export meat to the United States were audited. Two of these were slaughter establishments; the other one was conducting processing operations.

The last audit of the Romanian meat inspection system was conducted in June 1998. Six establishments were audited. Establishments 1, 2, 8, 12, and 68 were acceptable and Establishment 60 was evaluated as acceptable/re-review. Establishments 1, 8, and 60 were not certified as eligible to export meat and meat products to the United States at the time of the new audit. No major deficiencies were reported at that time. The major concerns from the previous audit:

1. Paper towels used for drying employees' hands were observed contacting the wastebasket at the hand washing facilities in Establishments 12 and 68. *This discrepancy was not corrected in both establishments. Both establishment officials agreed to take corrective actions immediately.*
2. Light was inadequate in the cooler in Establishment 12. *Corrected.*
3. Non-dripping condensation was seen above unpacked meat in Establishment 68. *Corrected.*
4. In the slaughter department of Establishment 68 in the process of skinning, cuts were made through the skin into the muscle with one stroke of the knife, without sanitizing the knife between the skin and muscle cuts. *Corrected.*
5. Oil contamination was observed on carcasses in the deboning room in Establishment 68, and contamination with unidentified foreign material was observed on carcasses in the deboning room in Establishment 2. *Corrected.*
6. Responsible employees' initials were missing on the thermograph of the can processing operation in Establishment 2. *Corrected.*
7. Street clothes of an exposed-product handler were not completely covered in Establishment 2. *Corrected.*

The major concerns from the new audit were the following:

1. The HACCP plan did not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequency with which these procedures will be performed. Neither establishment personnel nor GOR meat inspection officials were performing adequate ongoing verification activities of HACCP program in Establishments 2, 12, and 68.
2. The HACCP plan needed to be modified to ensure compliance with zero tolerance for visible fecal material on carcass in Establishments 2, and 68. The zero tolerance for fecal material on carcass requirement was not enforced by neither establishment officials nor GOR meat inspection officials and monitoring record was not maintained to verify this activity.
3. Monitoring frequencies and corrective actions to be followed in response to a deviation from a critical limit are not addressed adequately in the written HACCP plans of Establishment 2, 12, and 68.
4. Both establishment and inspection personnel had been unaware of the requirement for a pre-shipment review of all documentation pertaining to the monitoring of critical limits and, if appropriate, documentation that corrective actions were taken, included the proper disposition of the product, in each shipment eligible for export to the U.S. The auditor explained the requirements for this pre-shipment review in detail; GOR inspection and establishment officials agreed to comply with this requirement.
5. The following information was not recorded in the official record books for Laboratory Quality Assurance Program: Documentation of lot numbers and expiration dates for standard solutions, reagents, and media ingredients; the record books were not signed and verified by the supervisor each time before the newly prepared solutions were used by the technicians or chemists; and maintenance of records for corrective actions taken when unacceptable check sample results were reported.

Romania exports only canned hams to the United States. Restrictions are placed on Romanian beef and fresh pork due to presence of foot and mouth disease and hog cholera. Romania is considered to have a substantial risk associated with BSE. Poultry products are ineligible because USDA does not recognize Romania's poultry inspection system as equivalent.

Romania has not exported any meat and meat products to the United States of America since 1997.

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Romanian national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities preceding the on-site visits. All three Establishments 2, 12, and 68 were selected for on-site audits. The third was conducted by on-site visits to establishments. The fourth was a visit to three laboratories, and also all three performing analytical testing of field samples for the national residue testing program, and the other culturing field samples for the presence of microbiological contamination with *Salmonella*.

Program effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species. Romania's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in all of the three establishments audited and all were evaluated as acceptable. Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* and generic *E. coli*, are discussed later in this report.

HACCP-implementation deficiencies had been found in all three of the establishments visited (Ests. 2, 12, and 68). During this new audit, implementation of the required HACCP programs was now found to be deficient in all three (Ests. 2, 12, and 68) establishments visited. Details are provided in the Slaughter/ Processing Controls section later in this report.

Entrance Meeting

On February 22, an entrance meeting was held at the Food Hygiene and Public Health Directorate (FHPHD), National Sanitary Veterinary Agency (NSVA), Ministry of Agriculture and Food (MAF), office and was attended by Dr. Mircea Chertes, Director General, NSVA; Dr. Virgil Marcel Eftime, Deputy General Director, NSVA; Dr. Marilena Barcan, Director, FHPHD; Dr. Petre Negrea, Hygiene and Public Health Expert; Dr. Ciuciuc Anca, Veterinary Doctor; Dr. Ion Nisipas, State Inspector and Dr. Faizur R. Choudry, International Audit Staff Officer. Topics of discussion included the following:

1. Updates on the inspection system of Romania
2. The audit itinerary and travel arrangements
3. The U.S.-EC Veterinary Agreement issue
4. Delistment issues
5. Generic *E. coli* and *Salmonella* testing
6. HACCP implementation
7. SSOP implementation
8. Residue Questionnaire, Test Results (1999) and Plans (2000).
9. Enforcement- *Salmonella*/routine, Enforcement Report, Criminal Prosecution.
10. *Listeria Monocytogenes*. A) Do establishment's HACCP plans provide for control of *Listeria monocytogenes*? B) If not, has the establishments have substantial scientific evidence to demonstrate that controls are not needed? C) Do the establishments take corrective actions as necessary?
11. Species Testing Policy

A separate meeting was held at the U.S. Embassy in Bucharest on the same day and was attended by Mr. Anton Pavel, Agricultural Specialist, FAS and Dr. Faizur R. Choudry, International Audit Staff Officer. The meeting with Romanian inspection officials and FSIS establishment and laboratory requirements were discussed.

Headquarters Audit

There had been a change in the organizational structure or upper levels of inspection staffing since the last U.S. audit of Romania's inspection system in June, 1998. Dr. Nicolai Poparlan, Director General, has been replaced by Dr. Mircea Chertes.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. specifications. The FSIS auditor (hereinafter called “the auditor”) observed and evaluated the process.

The auditor conducted a review of inspection system documents pertaining to the establishments listed for records review. This records review was conducted at the meat inspection headquarters. The records review focused primarily on food safety hazards and included the following:

- Internal review reports.
- Supervisory visits to establishments that were certified to export to the U.S.
- Training records for inspectors and laboratory personnel.
- Label approval records such as generic labels.
- New laws and implementation documents such as regulations, notices, directives and guidelines.
- Sampling and laboratory analyses for residues.
- Pathogen reduction and other food safety initiatives such as SSOPs, HACCP programs, generic *E. coli* testing and *Salmonella* testing.
- Sanitation, slaughter and processing inspection procedures and standards.
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials.
- Export product inspection and control including export certificates.
- Enforcement records including examples of criminal prosecution, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

No concerns arose as a result of the examination of these documents.

Government Oversight

All inspection veterinarians and inspectors in establishments certified by Romania as eligible to export meat products to the United States were full-time FHPHD employees, receiving no remuneration from either industry or establishment personnel.

Establishment Audits

Three establishments were certified to export meat products to the United States at the time this audit was conducted. All three Establishments 2, 12, and 68 were visited for on-site audits. In all these establishments visited, both FHPHD inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products. With no exceptions, corrective actions were prompt and effective. Establishments 2, 12, and 68 were acceptable.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information about the following risk areas was also collected:

1. Government oversight of accredited, and approved, laboratories.
2. Intra-laboratory quality assurance procedures, including sample handling.
3. Methodology.

The Hygiene and Veterinary Public Institute reference laboratory in Bucharest was audited on March 2, 2000. The Regional Laboratory for Control of Residue and Microbiology in Timisoara was audited on February 24, 2000. The Regional Laboratory for Control of Residue and Microbiology in Iasi was audited on February 28, 2000. Except as noted below, effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. No compositing of samples was done.

The check sample program met FSIS requirements.

Laboratory Quality Assurance Program: In all the three residue testing and microbiology laboratories, the pages of official record books for standard solution/reagent/media ingredients for chlorinated hydrocarbons (CHC), polychlorinated biphenyls (PCBs), organophosphates (OP), trace elements (TE), hormones, chloramphenicol, ivermectin, and sulfonamides, were not serially numbered as required by Good Laboratory Practices and the following information was not recorded in the book for Laboratory Quality Assurance Program:

1. Lot numbers and expiration dates for standard solutions, reagents, and media ingredients were not recorded on the standard books.
2. The record book was not signed and verified by the supervisors each time before the newly prepared solutions were used by the technicians or chemists.
3. No record was maintained for the corrective actions taken when unacceptable check sample results were reported.

A training program for laboratory personnel was being held quarterly or more frequently if necessary by the Hygiene and Veterinary Public Health Institute in Bucharest.

Romania's microbiological testing for *Salmonella* was being performed in one government Laboratory in Bucharest and two regional laboratories in Timisoara and Iasi. All three of these laboratories were audited. The auditor determined that the system met the criteria

established for the use of private laboratories under FSIS's Pathogen Reduction/HACCP rule. These criteria are:

1. The laboratories were accredited/approved by the government, accredited by third party accrediting organization with oversight by the government, or a government contract laboratory.
2. The laboratories had properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record-keeping capabilities.
3. Results of analyses were being reported to the government or simultaneously to the government and establishment.

Establishment Operations by Establishment Number

The following operations were being conducted in the three establishments:

Establishment A-2: swine slaughter and de-boning, cooked sausages, and canned products

Establishment 12: cured and smoked pork products

Establishment 68: cattle and swine slaughter and de-boning, cured/dried/smoked products, and canned products.

SANITATION CONTROLS

Based on the on-site audits of establishments, Romania's inspection system had controls in place for water potability records; chlorination procedures; back-siphonage prevention; hand washing facilities; sanitizers; separation of operation; pest controls and monitoring; temperature control; lighting; work space; ventilation; maintenance and cleaning of over-product ceilings and equipment; dry storage areas; personal dress, habits, and hygiene; equipment sanitizing; welfare facilities; outside premises and product handling, transportation, and storage.

Sanitation Standard Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements.

Basic Establishment Facilities

1. Paper towels used for drying employees' hands were observed contacting the wastebasket at hand washing facilities in Establishments 12, and 68. Each establishment officials agreed to take corrective action immediately. This is a repeat deficiency from last audit.

2. All overhead screen vents were observed with accumulation of dust and black discoloration in the salami processing room in Establishment 2. Establishment officials ordered corrective actions immediately and proposed preventive measures to GOR inspection officials.
3. Numerous metal edible product containers were cracked and damaged in the boning and processing rooms in Establishment 68. Establishment officials ordered correction immediately.

Cross-Contamination

1. Blood, fat, and ingesta were found on the automatic hog viscera and offal conveyors after washing/sanitizing in the slaughter room. Dirty water was dripping on the viscera conveyor from employees' work platform at the evisceration station in Establishment 68. Establishment officials took temporary corrective actions and proposed modification to prevent recurrence to GOR inspection officials.
2. Beef carcasses were contacting work platforms and employees' boots at the carcass postmortem inspection and carcass trimming stations in Establishment 2. Establishment officials took corrective actions immediately.

ANIMAL DISEASE CONTROLS

With the exception listed below, Romania's inspection system had controls in place to ensure adequate animal identification, ante-mortem and post-mortem inspection procedures and dispositions, condemned and restricted product control, and procedures for sanitary handling of returned and rework product.

A few inedible product containers were not identified in the boning room in Establishment 2. Establishment officials ordered correction immediately.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit. Since 1973, Romania has been free of foot and mouth disease without vaccination. No positive case for Bovine Spongiform Encephalopathy (BSE) was reported in Romania. There were adequate animal identification and traceback, humane handling and slaughter of animals and control of condemned products.

RESIDUE CONTROLS

Romania's National Residue Testing Plan for 2000 was being followed, and was on schedule. The Romanian inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

GOR inspection service indicated that they did not receive Residue Questionnaire and requested a copy for response.

(Please see laboratory audit section)

SLAUGHTER/PROCESSING CONTROLS

The Romanian inspection system had controls in place to ensure adequate animal identification; antemortem inspection procedures; antemortem dispositions; humane slaughter; postmortem inspection procedures, postmortem dispositions; condemned product control; restricted product control; pre-boning trim; boneless meat reinspection; ingredients identification; control of restricted ingredients; formulations; packaging materials; inspector monitoring; processing schedules, equipment, and records; empty can inspection, filling procedures; container closure examination; post-processing handling; incubation procedures; processing defect actions-plant; and processing control-inspection.

HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements with the following major concerns:

1. Monitoring frequencies and corrective actions to be followed in response to a deviation from a critical limit are not addressed adequately in the written HACCP plan in Establishments 2, 12, and 68.
2. The HACCP plan does not state adequately the procedures that the establishment will use to verify that the plan is being effectively implemented. Neither establishment personnel nor GOR meat inspection officials were performing adequate ongoing verification activities of HACCP program in Establishments 2, 12, and 68.
3. The zero tolerance for visible fecal material on carcass was not monitored and enforced by the GOR meat inspection officials and establishment personnel in Establishments 2 and 68.
4. Both establishment and inspection personnel had been unaware of the requirement for a pre-shipment review of all documentation pertaining to the monitoring of critical limits and, if appropriate, documentation that corrective actions were taken, including the proper disposition of the product, in each shipment eligible for export to the U.S. The auditor explained the requirements for this pre-shipment review in detail. GOR inspection and establishment officials agreed to comply with this requirement.

GOR inspection and officials from Establishments 2, 12, and 68 agreed to take corrective actions for the discrepancies identified in their HACCP programs.

Testing for Generic *E. coli*

Romania has adopted the FSIS regulatory requirements for *E. coli* testing.

Two of the three establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing, and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements. Additionally, establishments had adequate controls in place to prevent meat products intended for Romanian domestic consumption from being commingled with products eligible for export to the U.S.

Control of *Listeria monocytogenes*

In response to the auditor's inquiry regarding the Romanian establishment officials evaluation of their HACCP programs to address the risk of *Listeria monocytogenes*, the meat inspection officials provided this information. All three establishments (Est. 2, 12, and 68) did not conduct a hazard analysis for *Listeria monocytogenes* to determine the food safety hazards reasonably likely to occur in the production process for ready-to-eat products or none of the establishments had scientific evidence to demonstrate that controls were not needed.

GOR inspection service has a surveillance program for ready-to-eat products for *Listeria monocytogenes* testing (one sample per month), but it is mandatory if product has to be exported. GOR inspection service indicated that in the future *Listeria* testing would be included in the establishments' HACCP plan.

ENFORCEMENT CONTROLS

Inspection System Controls

The GOR inspection system controls [ante-and post-mortem inspection procedures and dispositions, control of restricted product and inspection samples, control and disposition of dead, dying, diseased or disabled animals, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, and the importation of only eligible meat products from other countries for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

All of the three establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

The *Salmonella* testing program was audited and found to meet the basic FSIS regulatory requirements. The GOR inspection service has implemented *Salmonella* testing (one sample per month for beef and pork carcasses and one sample per week for ground meat).

Species Verification Testing

At the time of this audit, Romania was not exempt from the species verification testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements for export products to U.S. only.

Monthly Reviews

These reviews were being performed by the Romanian equivalent of Circuit Supervisors. All were veterinarians with at least 10 years of experience. Dr. Marilena Barcan, Director, FHPHD was in charge of the slaughter and processing establishments.

The internal review program was applied equally to both export and non-export establishments. Internal review visits were both announced in advance and sometimes not announced in advance, and were conducted, at times by individuals and at other times by a state veterinarian in a team review, at least once monthly. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the district offices and in Bucharest, and were routinely maintained on file for a minimum of 3 years.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify for eligibility to be reinstated, a commission is empowered to conduct an in-depth review, and the results are reported to Drs. Mircea Chertes, General Director, and Marilena Barcan, Director FHPHD, NSVA, for evaluation; they formulate a plan for corrective actions and preventive measures.

An organized training program for field inspection personnel was being offered quarterly by the Food Hygiene and Public Health Directorate; it included updated information on HACCP programs, SSOPs, problems relating to food hygiene, and public health and meat inspection.

Enforcement Activities

Controls were in place to ensure adequate export product identification, inspector verification, export certificates, a single standard of control throughout the establishments, inspection supervision as required, and adequate controls for security items, shipment security, species verification, and products entering the establishments from outside sources.

GOR inspection service has a regulation to enforce noncompliance when they determine that an establishment has not met the *Salmonella* standard. GOR inspection service uses Veterinary Police throughout the chain of distribution to detect and detain potentially hazardous foods in commerce to prevent their consumption and to investigate violations of law. Romania's equivalent of FSIS Regulatory and Enforcement Division. They are experienced veterinarians assigned in each District Office.

Exit Meetings

An exit meeting was conducted in Bucharest on March 3, 2000. The Romanian participants were Dr. Mircea Chertes, General Director, National Veterinary Agency (NVA), Ministry of Agriculture and Food; Dr. Marilena Barcan, Director, Food Hygiene and Public Health Directorate (FHPHD); Dr. Petre Negrea, Staff Officer; Dr. Ciuciuc Anca, Staff Officer; Dr. Ion Nisipasu, State Inspector; Dr. Sergiu Meica, Director, Hygiene and Veterinary Public Health Institute and Dr. Faizur R. Choudry, International Audit Staff Officer. One of the topics of discussion was the individual audit findings, as enumerated in the body of this report. The Romanian officials agreed to take the necessary steps to ensure that corrective actions and preventive measures, as promised during the audits and exit meetings in the individual establishments, would be implemented.

The following major concerns were discussed.

1. The HACCP plans did not adequately state the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequency with which these procedures will be performed.
2. The zero-tolerance policy for visible fecal material on carcass was not enforced by either establishment officials or GOR meat inspection officials.
3. Monitoring frequencies and corrective actions to be followed in response to a deviation from a critical limit were not addressed adequately in the written HACCP plans.
4. Both establishment and inspection personnel had been unaware of the requirement for a pre-shipment review of all documentation pertaining to the monitoring of critical limits and, if appropriate, documentation that corrective actions were taken, including the proper disposition of the product, for each shipment eligible for export to the U.S. The

auditor explained the requirements for this pre-shipment review in detail; GOR inspection officials indicated to implement this requirement promptly.

5. The following information was not recorded in the official record books for Laboratory Quality Assurance Program: documentation of lot numbers and expiration dates for standard solutions, reagents, and media ingredients was missing; the record books were not signed and verified by the supervisor each time before the newly prepared solutions were used by the technicians or chemists; and records were not maintained for corrective actions taken when unacceptable check sample results were reported.

CONCLUSION

The inspection system of Romania was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments, with the following exceptions. Three establishments were audited and all were acceptable. The deficiencies encountered during the on-site establishment audits were adequately addressed to the auditor's satisfaction. The FHPHD inspection officials reinforced the assurances made by field personnel during and at the conclusions of the on-site audits of the establishments, and stated that they would ensure prompt compliance.

The major concerns were the following:

1. The HACCP plans did not adequately state the procedures that the establishment will use to verify that the plan is being effectively implemented and the frequency with which these procedures will be performed.
2. The zero-tolerance policy for visible fecal material on carcass was not enforced by either establishment officials or GOR meat inspection officials.
3. Monitoring frequencies and corrective actions to be followed in response to a deviation from a critical limit were not addressed adequately in the written HACCP plans.
4. Both establishment and inspection personnel had been unaware of the requirement for a pre-shipment review of all documentation pertaining to the monitoring of critical limits and, if appropriate, documentation that corrective actions were taken, including the proper disposition of the product, for each shipment eligible for export to the U.S. The auditor explained the requirements for this pre-shipment review in detail; GOR inspection officials indicated to implement this requirement promptly.
5. The following information was not recorded in the official record books for Laboratory Quality Assurance Program: documentation of lot numbers and expiration dates for standard solutions, reagents, and media ingredients was missing; the record books were not signed and verified by the supervisor each time before the newly prepared solutions

were used by the technicians or chemists; and records were not maintained for corrective actions taken when unacceptable check sample results were reported.

Dr. Faizur R. Choudry
International Audit Staff Officer

(signed) Dr. Faizur R. Choudry

ATTACHMENTS

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs
- C. Data collection instrument for *E. coli* testing.
- D. Data collection instrument for *Salmonella* testing
- E. Laboratory audit form
- F. Individual Foreign Establishment Audit Forms
- G. Written Foreign Country's Response to the Draft Final Audit Report (when it becomes available)
- H. FSIS Response(s) to Foreign Country Comments (when it becomes available)

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used included the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

| Est. # | 1. Written program addressed | 2. Pre-op sanitation addressed | 3. Oper. sanitation addressed | 4. Contact surfaces addressed | 5. Frequency addressed | 6. Responsible indiv. Identified | 7. Documentation done daily | 8. Dated and signed |
|--------|------------------------------|--------------------------------|-------------------------------|-------------------------------|------------------------|----------------------------------|-----------------------------|---------------------|
| 2 | √ | √ | √ | √ | √ | √ | √ | √ |
| 12 | √ | √ | √ | √ | √ | √ | √ | √ |
| 68 | √ | √ | √ | √ | √ | √ | √ | √ |

Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a written procedure for testing for generic *E. coli*.
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

| Est. # | 1. Writ- ten pro- cedure | 2. Samp- ler des- ignated | 3. Samp- ling lo- cation given | 4. Pre- domin. species sampled | 5. Samp- ling at the req'd freq. | 6. Pro- per site or method | 7. Samp- ling is random | 8. Using AOAC method | 9. Chart or graph of results | 10. Re- sults are kept at least 1 yr |
|--------|--------------------------------|---------------------------------|---|---|---|-------------------------------------|-------------------------------|----------------------------|---------------------------------------|---|
| 2 | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ |
| 12 | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A | N/A |
| 68 | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ |

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. (except Est. TIF-119) was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
9. The HACCP plan was validated using multiple monitoring results.
10. *The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.*
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or does not include records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

| Est. # | 1. Flow diagram | 2. Hazard analysis | 3. All hazards identified | 4. Use & users included | 5. Plan for each hazard | 6. CCPs for all hazards | 7. Monitoring is specified | 8. Corr. act's are described | 9. Plan validated | 10. Adequate verific. procedures | 11. Adequate documentation | 12. Dated and signed |
|--------|-----------------|--------------------|---------------------------|-------------------------|-------------------------|-------------------------|----------------------------|------------------------------|-------------------|----------------------------------|----------------------------|----------------------|
| 2 | √ | √ | √ | √ | √ | √ | √1 | √2 | √ | √3 | √ | √ |
| 12 | √ | √ | √ | √ | √ | √ | √1 | √2 | √ | √3 | √ | √ |
| 68 | √ | √ | √ | √ | √ | √ | √1 | √2 | √ | √3 | √ | √ |

1. Monitoring frequencies for CCPs was not addressed adequately
2. Corrective actions to be followed in response to a deviation from a critical limit were not addressed adequately in the written HACCP plan.
3. Verification procedures and frequencies for these procedures not addressed adequately.

Data Collection Instrument for *Salmonella* testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. Salmonella testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

| Est. # | 1. Testing as required | 2. Carcasses are sampled | 3. Ground product is sampled | 4. Samples are taken randomly | 5. Proper site and/or proper prod. | 6. Violative est's stop operations |
|--------|------------------------|--------------------------|------------------------------|-------------------------------|------------------------------------|------------------------------------|
| 2 | √ | √ | N/A | √ | √ | √ |
| 12 | √ | N/A | √ | √ | N/A | √ |
| 68 | √ | √ | N/A | √ | √ | √ |

